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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,525	11/08/1999	PETER J. WILK	W07-431	5341

7590

07/19/2004

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EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/435,525

Applicant(s)

WILK, PETER J.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 19-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischman, et al., in view of Taylor, et al. As indicated in the previous action, the Fleischman, et al., Patent discloses a method comprising inserting a tensile member

Art Unit: 3763

into a patient, and inserting the tensile member into the patient's heart to compress areas near the atria of a patient's heart.

The applicant correctly argues that the Fleischman reference is directed solely to an operation performed on the atria of a patient heart, and furthermore, that said reference provides no teaching or suggestion to use the disclosed method for reducing ventricular volume. However, methods for reducing ventricular volume are conventional as evidenced by Taylor, et al. In figures 1-14C, Taylor shows various methods for the reduction of ventricular volume that include internal and external devices. These methods are comprised of (1) anchoring tensile members to opposing myocardial sidewalls, (2) placing a flanged element of the tensile member in contact with myocardial tissues, (3) placing a barbed element in contact with myocardial tissues, (4) aiming a tack at the outer surface of the heart, and (5) as figures 4c and 4d show, passing the tensile member through a trocar sleeve or cannula.

Based on the above observations, for a person of ordinary skill in the art, modifying the procedures disclosed in Fleischman, et al., to be applicable for the purpose of reducing ventricular volume would have been considered an obvious design choice in view of the teachings of Taylor, et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-8, 10-12, and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman, et al., in view of Clark, Hayhurst, and Taylor, et al. The Fleischman, et al., Patent does not utilize flanges and barbed elements. Additionally, the applicant correctly argues that the Fleischman reference is directed solely to an operation performed on the atria of a patient heart, and furthermore, that said reference provides no teaching or suggestion to use the disclosed method for reducing ventricular volume.

However, the use of flanges and barbed elements is conventional in the art as evidenced by the teachings of Clark and Hayhurst. The Clark Patent shows in figure 6-11F, the process of reducing the volume of a surgical area. Accordingly, based on the conventionality of the claimed enhancements mentioned above, it would have been obvious to modify the catheter device disclosed in Fleischman, et al. by adding the capabilities disclosed in the Clark and Hayhurst Patents. Conclusively, the mentioned enhancements would have been considered obvious design alternatives.

Finally, the applicant correctly argues that the Fleischman reference provides no teaching or suggestion to use the disclosed method for reducing ventricular volume. However, methods for reducing ventricular volume are conventional as evidenced by

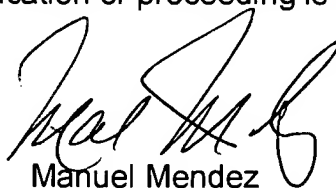
Art Unit: 3763

Taylor, et al. In figures 1-14C, Taylor shows various methods for the reduction of ventricular volume that include internal and external devices. These methods are comprised of (1) anchoring tensile members to opposing myocardial sidewalls, (2) placing a flanged element of the tensile member in contact with myocardial tissues, (3) placing a barbed element in contact with myocardial tissues, (4) aiming a tack at the outer surface of the heart, and (5) as figures 4c and 4d show, passing the tensile member through a trocar sleeve or cannula.

Based on the above observations, for a person of ordinary skill in the art, modifying the procedures disclosed in Fleischman, et al., Clark, and Hayhurst, to be applicable for the purpose of reducing ventricular volume would have been considered an obvious in view of the teachings of Taylor, et al.

Conclusion

In view of the use of the Taylor, et al., Patent in both of the rejections presented above, this action is not final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



Manuel Mendez
Primary Examiner
Art Unit 3763